

LEGISLATIVE BILL 432

Approved by the Governor May 25, 2001

Introduced by Brown, 6; Connealy, 16; Jensen, 20; Redfield, 12; Thompson, 14; Vrtiska, 1; Chambers, 11

AN ACT relating to genetic testing; to amend sections 13-607, 43-1414, 71-2620, 81-2010, and 81-2010.03, Reissue Revised Statutes of Nebraska, and sections 29-4105, 29-4115, and 71-519, Revised Statutes Supplement, 2000; to provide requirements relating to use and disposition of genetic testing and results relating to physicians, insurance, employers and employees, criminal investigations, paternity, and newborn infants; to provide requirements for laboratories performing human genetic and forensic testing; to provide penalties; and to repeal the original sections.
Be it enacted by the people of the State of Nebraska,

Section 1. (1) A physician or an individual to whom the physician has delegated authority to perform a selected act, task, or function shall not order a presymptomatic or predictive genetic test without first obtaining the written informed consent of the patient to be tested. Written informed consent consists of a signed writing executed by the patient or the legally authorized representative of the patient that confirms that the physician or individual acting under the delegated authority of the physician has explained, and the patient or his or her legally authorized representative understands:

(a) The nature and purpose of the presymptomatic or predictive genetic test;

(b) The effectiveness and limitations of the presymptomatic or predictive genetic test;

(c) The implications of taking the presymptomatic or predictive genetic test, including the medical risks and benefits;

(d) The future uses of the sample taken to conduct the presymptomatic or predictive genetic test and the genetic information obtained from the presymptomatic or predictive genetic test;

(e) The meaning of the presymptomatic or predictive genetic test results and the procedure for providing notice of the results to the patient; and

(f) Who will have access to the sample taken to conduct the presymptomatic or predictive genetic test and the genetic information obtained from the presymptomatic or predictive genetic test, and the patient's right to confidential treatment of the sample and the genetic information.

(2) The Department of Health and Human Services shall develop and distribute a model informed consent form for purposes of this section. The department shall include in the model form all of the information required under subsection (1) of this section. The department shall distribute the model form and all revisions to the form to physicians and other individuals subject to this section upon request and at no charge. The department shall review the model form at least annually for five years after the first model form is distributed and shall revise the model form if necessary to make the form reflect the latest developments in medical genetics. The department may also develop and distribute a pamphlet that provides further explanation of the information included in the model form.

(3) If a patient or his or her legally authorized representative signs a copy of the model informed consent form developed and distributed under subsection (2) of this section, the physician or individual acting under the delegated authority of the physician shall give the patient a copy of the signed informed consent form and shall include the original signed informed consent form in the patient's medical record.

(4) If a patient or his or her legally authorized representative signs a copy of the model informed consent form developed and distributed under subsection (2) of this section, the patient is barred from subsequently bringing a civil action for damages against the physician, or an individual to whom the physician delegated authority to perform a selected act, task, or function, who ordered the presymptomatic or predictive genetic test, based upon failure to obtain informed consent for the presymptomatic or predictive genetic test.

(5) A physician's duty to inform a patient under this section does not require disclosure of information beyond what a reasonably well-qualified physician licensed in Nebraska would know. A person acting under the

delegated authority of a physician shall understand and be qualified to provide the information required by subsection (1) of this section.

(6) For purposes of this section:

(a) Genetic information means information about a gene, gene product, or inherited characteristic derived from a genetic test;

(b) Genetic test means the analysis of human DNA, RNA, and chromosomes and those proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. A genetic test must be generally accepted in the scientific and medical communities as being specifically determinative for the presence, absence, or mutation of a gene or chromosome in order to qualify under this definition. Genetic test does not include a routine physical examination or a routine analysis, including a chemical analysis, of body fluids unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome. Genetic test does not include a procedure performed as a component of biomedical research that is conducted pursuant to federal common rule under 21 C.F.R. parts 50 and 56 and 45 C.F.R. part 46, as such regulations existed on the effective date of this act;

(c) Predictive genetic test means a genetic test performed for the purpose of predicting the future probability that the patient will develop a genetically related disease or disability; and

(d) Presymptomatic genetic test means a genetic test performed before the onset of clinical symptoms or indications of disease.

Sec. 2. (1)(a) Any hospital, medical, or surgical expense-incurred policy or certificate delivered, issued for delivery, or renewed in this state and (b) any self-funded employee benefit plan to the extent not preempted by federal law shall not require a covered person or his or her dependent or an asymptomatic applicant for coverage or his or her asymptomatic dependent to undergo any genetic test before issuing, renewing, or continuing the policy or certificate in this state.

(2) This section does not prohibit requiring an applicant for coverage to answer questions concerning family history.

(3) For purposes of this section:

(a) Clinical purposes includes:

(i) Predicting the risk of diseases;

(ii) Identifying carriers for single-gene disorders;

(iii) Establishing prenatal and clinical diagnosis or prognosis;

(iv) Prenatal, newborn, and other carrier screening, as well as testing in high-risk families;

(v) Testing for metabolites if undertaken with high probability that an excess or deficiency of the metabolite indicates or suggests the presence of heritable mutations in single genes; and

(vi) Other testing if the intended purpose is diagnosis of a presymptomatic genetic condition; and

(b) Genetic test means the analysis of human DNA, RNA, and chromosomes and those proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. A genetic test must be generally accepted in the scientific and medical communities as being specifically determinative for the presence, absence, or mutation of a gene or chromosome in order to qualify under this definition. Genetic test does not include a routine physical examination or a routine analysis, including a chemical analysis, of body fluids unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome.

Sec. 3. (1) For purposes of this section:

(a) Employee does not include an individual employed in the domestic service of any person;

(b) Employer means a person who has one or more employees;

(c) Genetic information means information about a gene, gene product, or inherited characteristic derived from a genetic test; and

(d) Genetic test means the analysis of human DNA, RNA, and chromosomes and those proteins and metabolites used to detect heritable or somatic disease-related genotypes or karyotypes for clinical purposes. A genetic test must be generally accepted in the scientific and medical communities as being specifically determinative for the presence, absence, or mutation of a gene or chromosome in order to qualify under this definition. Genetic test does not include a routine physical examination or a routine analysis, including a chemical analysis, of body fluids unless conducted specifically to determine the presence, absence, or mutation of a gene or chromosome.

(2) Except as otherwise required by federal law, an employer shall not:

(a) Fail or refuse to hire, recruit, or promote an employee or applicant for employment because of genetic information that is unrelated to the ability to perform the duties of a particular job or position;

(b) Discharge or otherwise discriminate against an employee or applicant with respect to compensation or the terms, conditions, or privileges of employment because of genetic information that is unrelated to the ability to perform the duties of a particular job or position;

(c) Limit, segregate, or classify an employee or applicant for employment in a way which deprives or tends to deprive an employee or applicant of employment opportunities or otherwise adversely affects the status of an employee or applicant because of genetic information that is unrelated to the ability to perform the duties of a particular job or position; or

(d) Require an employee or applicant for employment to submit to a genetic test or to provide genetic information as a condition of employment or promotion.

(3) Subsection (2) of this section does not prohibit an employee from voluntarily providing to an employer genetic information that is related to the employee's health or safety in the workspace. Subsection (2) of this section does not prohibit an employer from using genetic information received from an employee under this subsection to protect the employee's health or safety.

(4) This section shall not apply to the employment of an individual by his or her parent, spouse, or child.

Sec. 4. All laboratories performing human genetic testing for clinical diagnosis and treatment purposes shall be accredited by the College of American Pathologists or by any other national accrediting body or public agency which has requirements that are substantially equivalent to or more comprehensive than those of the college.

Sec. 5. Except as provided under section 81-2010, all forensic DNA laboratories performing work on behalf of the state or a political subdivision shall be accredited by the American Society of Crime Laboratory Directors-LAB-Laboratory Accreditation Board or the National Forensic Science Technology Center or by any other national accrediting body or public agency which has requirements that are substantially equivalent to or more comprehensive than those of the society or center.

Sec. 6. Section 13-607, Reissue Revised Statutes of Nebraska, is amended to read:

13-607. (1) The full out-of-pocket cost or expense that may be charged to a sexual assault victim in connection with a forensic medical examination shall be paid for by the law enforcement agency of a political subdivision if such law enforcement agency is the primary investigating law enforcement agency investigating the reported sexual assault.

(2) Except as provided under section 81-2010, all forensic DNA tests shall be performed by a laboratory which is accredited by the American Society of Crime Laboratory Directors-LAB-Laboratory Accreditation Board or the National Forensic Science Technology Center or by any other national accrediting body or public agency which has requirements that are substantially equivalent to or more comprehensive than those of the society or center.

Sec. 7. Section 29-4105, Revised Statutes Supplement, 2000, is amended to read:

29-4105. (1) The Nebraska State Patrol shall prescribe procedures to be used in the collection, submission, identification, analysis, storage, and disposition of DNA samples and DNA records under the DNA Detection of Sexual and Violent Offenders Act. These procedures shall include quality assurance guidelines for laboratories which submit DNA records to the State DNA Data Base and shall require that all laboratories be accredited by the American Society of Crime Laboratory Directors-LAB-Laboratory Accreditation Board or the National Forensic Science Technology Center or by any other national accrediting body or public agency which has requirements that are substantially equivalent to or more comprehensive than those of the society or center. The State DNA Data Base shall be compatible with the procedures specified by the Federal Bureau of Investigation, including the use of comparable test procedures, laboratory equipment, supplies, and computer software. The DNA records shall be securely stored in the State DNA Data Base and retained in a manner consistent with the procedures established by the Federal Bureau of Investigation.

(2) The Nebraska State Patrol may contract with the University of Nebraska Medical Center to establish the State DNA Sample Bank at the medical center and for DNA typing tests. The State DNA Sample Bank shall serve as the repository of DNA samples collected under the act. The University of Nebraska

Medical Center in contracting under the act is subject to the same restrictions and requirements of the act, insofar as applicable, as the Nebraska State Patrol, as well as any additional restrictions imposed by the patrol.

(3) The DNA samples and DNA records shall only be used by the Nebraska State Patrol to create a separate population data base comprised of DNA records obtained under the act after all personal identification is removed. The patrol may share or disseminate the population data base with other law enforcement agencies or forensic DNA laboratories which assist the patrol with statistical data bases. The population data base may be made available to and searched by other agencies participating in the Combined DNA Index System.

(4) Except for records and samples expunged under section 29-4109, the Nebraska State Patrol shall permanently retain DNA samples and records of an individual obtained under section 29-4106. Any other DNA samples and records related to forensic casework, other than those used for research or quality control, shall not be permanently retained but shall be retained only as long as needed for a criminal investigation or criminal prosecution.

(5) If the Nebraska State Patrol determines after analysis that a forensic sample has been submitted by an individual who has been eliminated as a suspect in a crime, the patrol or the law enforcement agency which submitted the sample shall destroy the DNA sample and record in the presence of a witness. After destruction, the patrol or law enforcement agency shall make and keep a written record of the destruction, signed by the individual who witnessed the destruction. After the patrol or the law enforcement agency destroys the DNA sample and record, it shall notify the individual if he or she is not a minor or the parent or legal guardian of a minor by certified mail that the sample and record have been destroyed. Destruction of a DNA sample and record under this section shall not be considered the offense of tampering with physical evidence under section 28-922.

Sec. 8. Section 29-4115, Revised Statutes Supplement, 2000, is amended to read:

29-4115. ~~Nothing in~~ Except as provided in section 29-4105, the DNA Detection of Sexual and Violent Offenders Act shall not limit or abrogate limits or abrogates any existing authority of peace officers to take, maintain, store, and utilize DNA samples for law enforcement purposes.

Sec. 9. Section 43-1414, Reissue Revised Statutes of Nebraska, is amended to read:

43-1414. (1) In any proceeding to establish paternity, the court may, on its own motion, or shall, on a timely request of a party, after notice and hearing, require the child, the mother, and the alleged father to submit to genetic testing to be performed on blood or any other appropriate ~~tissue~~ genetic testing material. Failure to comply with such requirement for genetic testing shall constitute contempt and may be dealt with in the same manner as other contempts. If genetic testing is required, the court shall direct that inherited characteristics be determined by appropriate testing procedures and shall appoint an expert in genetic testing and qualified as an examiner of genetic markers to analyze and interpret the results and to report to the court. The court shall determine the number of experts required.

(2) In any proceeding to establish paternity, the Director of Health and Human Services, county attorneys, and authorized attorneys have the authority to require the child, the mother, and the alleged father to submit to genetic testing to be performed on blood or any other appropriate ~~tissue~~ genetic testing material. All genetic testing shall be performed by a laboratory accredited by the College of American Pathologists or any other national accrediting body or public agency which has requirements that are substantially equivalent to or more comprehensive than those of the college.

(3) Except as authorized under sections 43-1414 to 43-1418, a person shall not disclose information obtained from genetic paternity testing that is done pursuant to such sections.

(4) If an alleged father who is tested as part of an action under such sections is found to be the child's father, the testing laboratory shall retain the genetic testing material of the alleged father, mother, and child for no longer than the period of years prescribed by the national standards under which the laboratory is accredited. If a man is found not to be the child's father, the testing laboratory shall destroy the man's genetic testing material in the presence of a witness after such material is used in the paternity action. The witness may be an individual who is a party to the destruction of the genetic testing material. After the man's genetic testing material is destroyed, the testing laboratory shall make and keep a written record of the destruction and have the individual who witnessed the destruction sign the record. The testing laboratory shall also expunge its

records regarding the genetic paternity testing performed on the genetic testing material in accordance with the national standards under which the laboratory is accredited. The testing laboratory shall retain the genetic testing material of the mother and child for no longer than the period of years prescribed by the national standards under which the laboratory is accredited. After a testing laboratory destroys an individual's genetic testing material as provided in this subsection, it shall notify the adult individual, or the parent or legal guardian of a minor individual, by certified mail that the genetic testing material was destroyed.

(5) A testing laboratory is required to protect the confidentiality of genetic testing material, except as required for a paternity determination. The court and its officers shall not use or disclose genetic testing material for a purpose other than the paternity determination.

(6) A person shall not buy, sell, transfer, or offer genetic testing material obtained under sections 43-1414 to 43-1418.

(7) A testing laboratory shall annually have an independent audit verifying the contracting laboratory's compliance with this section. The audit shall not disclose the names of, or otherwise identify, the test subjects required to submit to testing during the previous year. The testing laboratory shall forward the audit to the department.

(8) Any person convicted of violating this section shall be guilty of a Class IV misdemeanor for the first offense and a Class III misdemeanor for the second or subsequent offense.

(9) For purposes of sections 43-1414 to 43-1418, an expert in genetic testing means a person who has formal doctoral training or postdoctoral training in human genetics.

Sec. 10. Section 71-519, Revised Statutes Supplement, 2000, is amended to read:

71-519. (1) All infants born in the State of Nebraska shall be screened for phenylketonuria, primary hypothyroidism, biotinidase deficiency, and such other metabolic diseases as the Department of Health and Human Services may from time to time specify. Confirmatory tests shall be performed in the event that a presumptive positive result on the screening test is obtained.

(2) The attending physician shall collect or cause to be collected the prescribed blood specimen or specimens and shall submit or cause to be submitted the same to a laboratory for the performance of such tests within the period prescribed by the department. In the event a birth is not attended by a physician, the person registering the birth shall cause such tests to be performed within the period prescribed by the department. The laboratory shall within the period prescribed by the department perform such tests as are prescribed by the department on the specimen or specimens submitted and report the results of these tests to the physician, if any, and the hospital. The laboratory shall report to the department the results of such tests that are presumptive positive or confirmed positive within the period and in the manner prescribed by the department.

(3) The hospital shall record the collection of specimens for tests for metabolic diseases and the reporting of the results of such tests or the absence of such report. The hospital shall report the results of such tests to the department within the period and in the manner prescribed by the department.

(4) The department shall do all of the following in regard to the blood specimens taken for purposes of conducting the tests required under subsection (1) of this section:

(a) Develop a schedule for the retention and disposal of the blood specimens used for the tests after the tests are completed. The schedule shall meet the following requirements:

(i) Be consistent with nationally recognized standards for laboratory accreditation and federal law;

(ii) Require that the disposal be conducted in the presence of a witness. For purposes of this subdivision, the witness may be an individual involved in the disposal or any other individual; and

(iii) Require that a written record of the disposal be made and kept and that the witness sign the record; and

(b) With the written consent of the parent or legal guardian of the infant, allow the blood specimens to be used for medical research during the retention period as long as the medical research is conducted in a manner that preserves the confidentiality of the test subjects and is consistent to protect human subjects from research risks under subpart A of part 46 of 45 C.F.R., as such regulations existed on the effective date of this act.

(5) The department shall prepare written materials explaining the requirements of this section. The department shall include the following

information in the pamphlet:

(a) The nature and purpose of the testing program required under this section, including, but not limited to, a brief description of each condition or disorder listed in subsection (1) of this section;

(b) The purpose and value of the infant's parent, guardian, or person in loco parentis retaining a blood specimen obtained under subsection (6) of this section in a safe place;

(c) The department's schedule for retaining and disposing of blood specimens developed under subdivision (4)(a) of this section; and

(d) That the blood specimens taken for purposes of conducting the tests required under subsection (1) of this section may be used for medical research pursuant to subdivision (4)(b) of this section.

(6) In addition to the requirements of subsection (1) of this section, the attending physician or person registering the birth may offer to draw an additional blood specimen from the infant. If such an offer is made, it shall be made to the infant's parent, guardian, or person in loco parentis at the time the blood specimens are drawn for purposes of subsection (1) of this section. If the infant's parent, guardian, or person in loco parentis accepts the offer of an additional blood specimen, the blood specimen shall be preserved in a manner that does not require special storage conditions or techniques, including, but not limited to, lamination. The attending physician or person making the offer shall explain to the parent, guardian, or person in loco parentis at the time the offer is made that the additional blood specimen can be used for future identification purposes and should be kept in a safe place. The attending physician or person making the offer may charge a fee that is not more than the actual cost of obtaining and preserving the additional blood specimen.

(7) The person responsible for causing the tests to be performed under subsection (2) of this section shall inform the parent or legal guardian of the infant of the tests and of the results of the tests and provide, upon any request for further information, at least a copy of the written materials prepared under subsection (5) of this section.

(8) Dietary and therapeutic management of the infant with phenylketonuria, primary hypothyroidism, biotinidase deficiency, or such other metabolic diseases as the department may from time to time specify shall be the responsibility of the child's parent, guardian, or custodian with the aid of a physician selected by such person.

Sec. 11. Section 71-2620, Reissue Revised Statutes of Nebraska, is amended to read:

71-2620. The Department of Health and Human Services Regulation and Licensure may enter into agreements, not exceeding one year in duration, with any other governmental agency relative to the provision of certain laboratory tests and services to the agency. Such services shall be provided as stipulated in the agreement and for such fee, either lump sum or by the item, as is mutually agreed upon and as complies with the provisions of section 71-2619. All laboratories performing human genetic testing for clinical diagnosis and treatment purposes shall be accredited by the College of American Pathologists or by any other national accrediting body or public agency which has requirements that are substantially equivalent to or more comprehensive than those of the college.

Sec. 12. Section 81-2010, Reissue Revised Statutes of Nebraska, is amended to read:

81-2010. A criminalistics laboratory is hereby established within the Nebraska State Patrol, under the direction of the Superintendent of Law Enforcement and Public Safety. The laboratory shall perform services necessary for the recognition and proper preservation, identification, and scientific analysis of evidence materials pertaining to the investigation of crimes. By October 1, 2003, the laboratory shall have met the requirements for accreditation by the American Society of Crime Laboratory Directors-LAB-Laboratory Accreditation Board or the National Forensic Science Technology Center and have applied for accreditation.

Sec. 13. Section 81-2010.03, Reissue Revised Statutes of Nebraska, is amended to read:

81-2010.03. (1) The full out-of-pocket cost or expense that may be charged to a sexual assault victim in connection with a forensic medical examination shall be paid for by the Nebraska State Patrol if the patrol is the primary investigating law enforcement agency investigating the reported sexual assault.

(2) Except as provided under section 81-2010, all forensic DNA tests shall be performed by a laboratory which is accredited by the American Society of Crime Laboratory Directors-LAB-Laboratory Accreditation Board or the National Forensic Science Technology Center or by any other national

accrediting body or public agency which has requirements that are substantially equivalent to or more comprehensive than those of the society or center.

Sec. 14. Original sections 13-607, 43-1414, 71-2620, 81-2010, and 81-2010.03, Reissue Revised Statutes of Nebraska, and sections 29-4105, 29-4115, and 71-519, Revised Statutes Supplement, 2000, are repealed.